IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION *This document relates to:* Track Three Cases	MDL 2804 Case No. 17-d-2804 Hon. Dan Aaron Polster

DEFENDANTS' OMNIBUS BRIEF IN OPPOSITION
TO PLAINTIFFS' MOTIONS *IN LIMINE*

No. 44: Exclude any reference to prescription opioids as "legal" drugs or distinguishing them from "illegal" drugs.

Plaintiffs seek to preclude Defendants from describing the pain medications they distribute and dispense as "legal." Doc. 3830 at 1. Plaintiffs further seek to preclude Defendants from distinguishing these medications from illegal drugs and even from describing the medications as approved by the FDA. *Id.* at 1-2. In so doing, Plaintiffs seek to preclude Defendants from stating true facts or, at a minimum, from making fair argument and drawing fair inferences. In effect, they seek to preclude an entire defense. Therefore, the Court should deny the motion. If any relief is warranted on this issue, it should go the other way—Plaintiffs should be precluded from arguing that the pain medications at issue are *not* legal and from arguing that they *are* akin to illegal street drugs like heroin.

First, the pain medications in question *are* legal. This is fact. The FDA has approved each of the medications at issue as safe and effective. 21 C.F.R. § 314.105(c); Ex. A, Tr. of Track Three Deposition of FDA Official Teresa Toigo at 23-36. Likewise, DEA has determined that each of the medications at issue has a "currently accepted medical use," that doctors may prescribe them, that distributors may distribute them, and that pharmacies may dispense them. 21 U.S.C. § 812(b)(2); 21 C.F.R. §§ 1301.11, 1306.11. It is absurd to suggest that Defendants should not be permitted to state these basic facts. And it is specious to argue that medications approved by FDA and DEA may not be called "legal."

These legal medications contrast sharply with illegal opioids like heroin. FDA has *not* approved heroin as a safe and effective medication. DEA, in fact, has determined that it has "no currently accepted medical use." 21 U.S.C. § 812(b)(1). Doctors are not permitted to prescribe heroin to patients, distributors are not permitted to ship heroin to pharmacies, and pharmacists are not permitted to dispense it to patients. Heroin, therefore, *is* clearly distinguishable from the

approved (and legal) pain medications at issue, and there is no basis to preclude Defendants from saying so. Indeed, Plaintiffs' own officials and experts have recognized the distinction.[1]

Plaintiffs' only argument to the contrary is that pain medications are regulated and that doctors, pharmacists, and even patients may violate the regulations applicable to such medications. The same obviously can be said for any regulated product or activity. Indeed, to say that the regulated status of pain medications makes them something other than "legal" is no different than saying that an automobile is something other than "legal" simply because a license is required to drive it and certain acts like speeding and drunk driving are not permitted. In this regard, Plaintiffs completely ignore the fact that the manufacture, distribution, and use of prescription opioids can be and in most cases is legal,[2] while the manufacture, distribution, and use of illegal drugs like heroin never can be legal.

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[1] *See, e.g.*, Ex. B, Tr. of Track Three Deposition of Trumbull County Official April Caraway at 68 (Q: Do you understand that there are both prescription and illicit opioids? You understand that, right? A: Yes. Q: And you're aware that prescription opioids are legal medications in the United States, correct? A: Correct.) (objection omitted); Ex. C, Tr. of Track Three Deposition of Lake County Official Kimberly Fraser at 56 (Q: And do you understand there are both prescription opioids and illicit opioids? A: Yes, I do … Q: Are you aware that prescription opioids are legal medications? A: Yes, I am") (objection omitted); Doc. 3844-1, Expert Report of David Cutler ¶¶ 20, 21, 25, 46, 62, 71, 101, 120-21 (distinguishing between "prescription opioids," "prescription opioid mortality," and the "prescription opioid crisis," on the one hand, and "illicit opioids," "illicit opioid morality," and the "illicit opioid crisis," on the other hand); *see also* Ex. D, Tr. of Track Three Deposition of Melanie Blasko, President and CEO of Lake Geauga Recovery Center, at 48-49 ("Q. What is your understanding of [what an opioid is]? A. Well, they include painkillers, legally prescribed, so oxycodone, Oxycontin. And then illegal, heroin, those that are synthetic, fentanyl, some of the other street drugs. Q. Okay. So you understand there's both prescription and illicit opioids, correct? A. Yes. Q. And you're aware that prescription opioids are legal medications, correct? A. Yes.").

[2] DEA has made clear that the overwhelming majority of prescriptions are written for a legitimate medical purpose and, therefore, lawful. *See, e.g.*, Ex. E, Testimony of Robert W. Patterson, DEA Acting Administrator, Hearing before the House of Representatives Committee on the Judiciary, May 8, 2018, at 32 ("I look at the vast majority of doctors; 99.99 percent are all trying to do right by their patients.")

Second, at a bare minimum, it is most certainly fair argument—and fair inference—for Defendants to describe pain medications as "legal" given that they are approved by FDA and DEA. It would be error to preclude Defendants from making such argument and drawing such an inference. *See United States v. Carter*, 236 F.3d 777, 784 (6th Cir. 2001) ("counsel has the freedom at trial to argue reasonable inferences from the evidence"); *see generally* Doc. 3058 (order of this Court stating that "it intends to have 'a very wide strike zone' for evidence about what the federal government, the DEA, and the Food and Drug Administration ('FDA') did or did not do in connection with opioid regulation").

Plaintiffs' counterpoints go to weight, not admissibility. If a witness or defense attorney characterizes government-approved pain medication as legal and Plaintiffs wish to attack that characterization as overly simple or incomplete, they are free to try.

Third, granting Plaintiffs' motion would risk striking a key defense. Even Plaintiffs do not contend that pain medications distributed and dispensed by a DEA registrant in compliance with the Controlled Substances Act ("CSA") are illegal. Defendants will present evidence that their distribution and dispensing complied with the CSA and, therefore, was legal. Plaintiffs are free to argue to the contrary. But they cannot create an unequal playing field by precluding Defendants from truthfully stating that the pain medications they distributed and dispensed were "legal" prescription medications approved by FDA and DEA. Without that foundation, Defendants will be prevented from showing that their distribution and dispensing complied with the CSA.

For these reasons, Plaintiffs' motion must be denied. To the contrary, Plaintiffs themselves must be precluded from arguing, falsely and misleadingly, that the pain medications at issue are *not* legal and that they are comparable to heroin and other illegal street drugs.

No. 45: Exclude any reference to efforts or actions of any Defendant, or its affiliates or employees, in connection with in-store "good deeds" or corporate conduct unrelated to opioids.

Plaintiffs seek to exclude any reference "to efforts or actions of any Defendant, or its affiliates or employees, in connection with in-store 'good deeds' or corporate conduct unrelated to opioids." Doc. 3830 at 3. The Court previously has granted in part two similar motions filed by the Track One plaintiffs. *See* Doc. 3508 at 68-69 ("[E]vidence that the parties and/or their employees are 'good citizens' and do good deeds such as providing scholarships, community service, or charitable contributions is not relevant to the issues in this case (unless another party offers evidence to the contrary)."); Doc. 3546 at 16-17 ("Defendants' 'good deeds' related to COVID-19 similarly are irrelevant unless Plaintiffs offer evidence to the contrary."). Plaintiffs ask the Court to "extend" these prior rulings to "non-opioid-related in-store activities or promotions" as well as any "corporate policies or decisions regarding non-opioid products." Doc. 3830 at 3. .

Testimony regarding "non-opioid-related in-store activities" and "corporate policies or decisions regarding non-opioid-related products" is obviously not the equivalent of testimony regarding corporate "good deeds." The Court should reject Plaintiffs' attempt to stretch the "good deeds" ruling beyond its plain meaning.

Plaintiffs' motion as to non-opioid-related matters or even "good deeds" also is premature. Whether Defendants will seek to introduce such evidence depends on whether Plaintiffs open the door to it. Thus, should the Court extend its prior "good deeds" rulings to non-opioid-related activities, policies, or decisions, it also should clarify, as it did in those prior rulings, that such evidence may be introduced if Plaintiffs open the door to it.

Plaintiffs have given every indication that they will in fact open the door at trial. Throughout discovery in Track Three, Plaintiffs themselves have attempted to develop evidence regarding matters having nothing to do with Defendants' distribution or dispensing of prescription opioid medications. For example, Plaintiffs have attempted to elicit deposition testimony about Defendants' profits, alleging that Defendant prioritize profits over patient safety, and have included on their exhibit list documents containing information about Defendants' profits; Plaintiffs have attempted to elicit deposition testimony regarding the compensation of Defendants' executives, trying to paint Defendants as greedy corporations; Plaintiffs have requested documents and attempted to elicit deposition testimony regarding pharmacy operations that do not involve the filling of prescriptions for opioid medications (*e.g.*, giving flu and COVID-19 vaccinations and the filling of prescriptions for non-opioid medications); and Plaintiffs have requested documents and attempted to elicit deposition testimony regarding so-called "performance metrics" that do not concern the filling of prescriptions for opioid medications (*e.g.*, performance metrics related to retrieval of voicemails). Thus, if Plaintiffs introduce evidence attempting to show that Defendants prioritized profits over patients or that Defendants' decision-making was infected with corporate greed—allegations that would be utterly baseless—then Defendants should be permitted to introduce counter evidence that fairly meets Plaintiffs' arguments. And if Plaintiffs otherwise introduce evidence related to subjects that do not concern the distribution or dispensing of prescription opioid medications, then Defendants should be permitted to introduce counter evidence that meets those subjects as well.

Plaintiffs seek an uneven playing field, where they are free to attack Defendants on all fronts but Defendants are left unable to defend themselves on some of those fronts. The Court should reject such a strategy and deny Plaintiffs' motion.

No. 46: Exclude any reference to the *Frye* hearing testimony of Dr. David Kessler on August 14, 220 in the New York opioid litigation.

No ruling on this motion is necessary. As part of ongoing efforts to narrow deposition designations before trial, Defendants will withdraw their designations of Dr. Kessler's testimony at the *Frye* hearing in New York. Consequently, this motion is moot.

No. 47: Admit Plaintiffs' Rule 1006 summaries.

The Court should deny Plaintiffs' motion as premature. As the Court knows, the parties already stipulated to a process for exchanging proposed Rule 1006 summaries, objecting to those summaries, and submitting unresolved objections to the Court for resolution at the proper time. *See* Doc. 3595-2, Joint Trial Exhibit Stipulation at 6. Plaintiffs acknowledge that they intend to "submit additional Rule 1006 summaries" on the "stipulated deadline" and are submitting this incomplete set of "potential Rule 1006 summaries" in hopes of obtaining "threshold rulings" from the Court. *See* Omnibus Br. at 6-7 n.4.[3] But there is no reason to issue blanket rulings on subsets of summaries before the parties' stipulated process has run its course and before the Court and parties know what summaries Plaintiffs will actually use at trial and how Plaintiffs will actually use them.

First, Plaintiffs' motion is premature. As Plaintiffs are well aware, their expert who prepared the subset of summaries, Craig McCann, is subject to an unresolved *Daubert* motion. Doc. 3866. And in just the few weeks since filing their motion, the severance of Rite Aid has rendered a number of Plaintiffs' potential Rule 1006 summaries inaccurate. *See* Doc. 3894. While Plaintiffs put great weight on a ruling about a different set of Rule 1006 summaries created by

[3] The stipulated deadline was originally August 27, 2021. Doc. 3595-2 at 6. Following the severance of Rite Aid, the parties "agreed to a 1-week extension" of that deadline to September 3, 2021. Ex. F, 8/27/21 Email from T. Fumerton to Special Master Cohen.

McCann in Track Two—a bench not jury trial—that ruling was not made in advance of trial. Judge Faber made his ruling only after the charts had been used at trial and a foundation had been laid through McCann's trial testimony. *See* Ex. G, 8/18/21 Authenticity Hearing Tr. at 86:3-10 (counsel for Plaintiffs acknowledging that Judge Faber analyzed and admitted the Track Two charts only after "several days of testimony by Dr. McCann to lay the foundation for the admissibility of the process[ed] data and 1006s created from that process[ed] data").[4] And Special Master Cohen already has informed Plaintiffs that proper foundation will have to be laid at trial for what McCann did to adjust the raw ARCOS data, which is part of "the normal presentation of evidence." *Id.* at 88:25-89:4. Moreover, Plaintiffs can only admit as a Rule 1006 summary any chart that is an "accurate" or "correct" summary of existing data. They cannot admit a chart that depends on figures manipulated through expert analysis, as some of Plaintiffs' charts based on expert-adjusted ARCOS data do.

All of this is fully consistent with the Rule 1006 requirements outlined in *United States v. Bray*, 139 F.3d 1104 (6th Cir. 1998), including that "a summary document must be properly introduced ***before*** it may be admitted into evidence." *Id.* at 1110 (emphasis added); *see also id.* ("In order to lay a proper foundation for a summary, the proponent should present the testimony

[4] Plaintiffs appear to believe that laying a foundation at trial is too great a burden. But there is no reason why Plaintiffs should have to spend "several days of testimony" to lay the foundation for McCann's data sources and what he did with them—as the Track Two plaintiffs chose to do. More fundamentally, the fact that foundation may have been laid for different summaries in a separate case against different defendants does not obviate the need to lay a foundation in this case.

of the witness who supervised its preparation."). Until a proposed summary has been properly introduced and a foundation has been laid at trial, admission is necessarily premature.[5]

Second, Plaintiffs improperly seek a blanket ruling when any decision must necessarily be made chart by chart and in the context of how each is presented at trial. The question will never be whether subsets of voluminous data can, as a general matter, be admitted, but whether a specific proffered summary in the context of Plaintiffs' presentation should be. Some may be admissible, some may be admissible after mutually agreed-upon modifications, and others may not be admissible at all. And, of course, each summary may be admitted only after a foundation has been laid for that summary at trial and any other evidentiary objections (such as relevance and prejudice) have been addressed. *Bray*, 139 F.3d at 1110; Fed. R. Evid. 401, 402, 403.

As to the proffered set of thirteen Rule 1006 summaries, Defendants expect that Plaintiffs will submit revised versions of those summaries tomorrow. Defendants will raise any objections to whether those charts meet the requirements of Rule 1006 as part of the parties' stipulated process, and expect that some of those objections will be capable of resolution through the meet-and-confer process. Defendants expressly reserve the right to object that any such revised summaries are otherwise inadmissible under the Federal Rules of Evidence.

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[5] In New York, Justice Garguilo reiterated these same principles in response to the plaintiffs' attempt to introduce summary exhibits through McCann. *See* Ex. H, 8/20/21 Court Notice re McCann Testimony at 4 ("Once again, the parties seek rulings in advance about . . . exhibits before an opportunity to hear foundation testimony has taken place. Such rulings must necessarily await trial where the Court will have an opportunity to hear the proffered foundation evidence, and any pertinent objections thereto. Similarly, with respect to Dr. McCann's proposed exhibits, any rulings must necessarily await the offer of the particular exhibit to determine whether a proper foundation has been laid, and the Court has heard the objections of Defendants, and any *voir dire* that may be granted the Defendants with respect to a particular exhibit.").

For now, the Court should deny Plaintiffs' motion without prejudice, deferring ruling on any proposed Rule 1006 summaries until after the parties meet and confer pursuant to their stipulation, after the Court has resolved Defendants' *Daubert* motion as to McCann's testimony, after the Court and parties alike know which Defendants will be at the Track Three trial, what summaries Plaintiffs actually seek to use with McCann, and how they will be used, and after Plaintiffs have attempted to lay a foundation for those summaries.

Dated: September 2, 2021

Respectfully submitted,

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